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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,632	12/19/2001	Steve Sichuan He	38-21(51837)B	8916
7590 11/19/2004			EXAMINER	
Lawrence M. Lavin, Jr. Patent Department, E2NA Monsanto Company 800 N. Lindbergh Boulevard St. Louis, MO 63167			BAUM, STUART F	
			ART UNIT	PAPER NUMBER
			1638	
DATE MAILED: 11/19/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/024,632

Applicant(s)

HE ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6 is/are allowed.
- 6) ☒ Claim(s) 3-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/19/01, 5/6/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The amendment filed 8/19/2004 has been entered.
2. Claims 3-6 are pending.  
Claims 1-2 and 7-34 have been canceled.
3. Claims 3-6 including SEQ ID NO:2 are examined in the present office action.
4. Rejections and objections not set forth below are withdrawn.
5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

### ***Restriction/Election***

6. Applicants acknowledge the finality of the election requirement to a single nucleotide sequence but maintain their traversal. Applicants contend that election of a single nucleotide sequence is improper and no serious burden would result by the search and examination of all six nucleotide sequences in the claims (page 4, 3<sup>rd</sup> paragraph).

The Office contends that the restriction requirement has been made final and that Applicants have the prerogative to petition the restriction requirement.

### ***Written Description***

7. Claims 3-5 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set

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forth in the Official action mailed 5/19/2004. Applicant's arguments filed 8/19/2004 have been fully considered but they are not persuasive.

Applicants contend that the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, i.e., to ensure that the inventors actually invented what is claimed. Applicants contend that they need not "describe", in the sense of Section 112, all things that are encompassed by the claims (page 7, 2<sup>nd</sup> full paragraph).

Applicants contend that in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules (e.g., "essential regions") be disclosed (page 8, top paragraph). Applicants contend that each nucleic acid molecule within a claimed genus does not need to be described by its complete structure (page 8, 1<sup>st</sup> full paragraph). Applicants contend that they have provided a detailed chemical structure by way of the claimed nucleic acid molecule encoding SEQ ID NO:2, as well as complements and specified variations thereof (*Ibid*). Applicants contend that the specification teaches vectors, single nucleotide polymorphisms (SNPs), nucleic acid molecules encoding amino acid sequences having conservative substitutions, fusion proteins, protein homologues and hybridization conditions (paragraph bridging pages 8 and 9). Applicants contend that they have provided a detailed chemical structure, e.g., nucleic acid sequences encoding SEQ ID NO:2 and that nucleic acid molecules falling within the scope of claims 3-5 are readily identifiable. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point (page 10, 2<sup>nd</sup> full paragraph).

The Office contends that Applicants have disclosed a nucleic acid sequence, SEQ ID NO:1, encoding SEQ ID NO:2, which fulfills the written description requirement for claim 6

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drawn to an isolated nucleic acid sequence which encodes an amino acid sequence comprising SEQ ID NO:2. But, for claims drawn to nucleic acid molecules encoding a polypeptide having an amino acid sequence that is substantially identical to SEQ ID NO:2, Applicants have not fulfilled the written description requirement. Applicants define "substantially identical" to mean that an amino acid sequence has at least 60% sequence identity compared to another sequence (see page 15, lines 10-18 of the specification). Applicants have not disclosed any nucleic acid sequence encoding a polypeptide having at least 60% sequence identity with SEQ ID NO:2, or a nucleic acid sequence which can hybridize under stringent conditions to a nucleic acid sequence encoding a polypeptide having 60% sequence identity to SEQ ID NO:2, or a nucleic acid sequence encoding an amino acid sequence comprising SEQ ID NO:2 containing conservative amino acid substitutions or Applicants have not disclosed essential regions of SEQ ID NO:2 that are required for the proper activity of the protein, or lastly, Applicants have not disclosed a representative number of sequences encoding a protein with the same activity as SEQ ID NO:2 wherein one skilled in the art would be able to determine the essential domains that are required for the proper activity of the protein. Given the specified deficiencies, Applicants have not fulfilled the written description requirements for claims 3-5.

### ***Scope of Enablement***

8. Claims 3-5 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated nucleic acid sequences encoding SEQ ID NO:2 and plant transformation therewith, does not reasonably provide enablement for nucleic acid sequences encoding a polypeptide having an amino acid sequence that is substantially identical

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to SEQ ID NO:2, an isolated nucleic acid molecule comprising a nucleotide sequence that hybridizes under stringent conditions to a nucleic acid encoding a polypeptide having substantial identity to SEQ ID NO:2 or an isolated nucleic acid sequence which encodes an amino acid sequence comprising SEQ ID NO:2 containing conservative amino acid substitutions and plant transformation therewith. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/19/2004. Applicant's arguments filed 8/19/2004 have been fully considered but they are not persuasive.

Applicants contend that an analysis of the criteria presented by *In re Wands* supports Applicants' position that no undue experimentation would be required to make and use the claimed invention (sentence bridging pages 11 and 12). Applicants contend that because of the extensive knowledge required for "make and test" experimentation to which a person of ordinary skill in the art has access, performing routine and well-known steps cannot create undue experimentation, even if it is laborious (page 12, 1<sup>st</sup> full paragraph). Applicants contend that the specification provides guidance, for example, to percent sequence identity, and discusses the use of the claimed SEQ ID NO to isolate additional sequences within a genome (page 12, 2<sup>nd</sup> full paragraph). Applicants contend that the specification teaches methods of identifying other nucleic acid sequences that can be used in the invention, and methods to confirm introduction of said nucleic acid sequences into hosts (paragraph bridging pages 12 and 13). Applicants contend that the specification discloses sufficient guidance to render results predictable (page 12 1<sup>st</sup> full paragraph). Applicants contend that the specification discloses to one of skill in the art which

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sequences would be useful without undue experimentation (page 13, 2<sup>nd</sup> full paragraph).

Applicants contend that the analysis of the *Wands* factors as discussed above, conclusively establishes that one of ordinary skill in the art would be able to make and use the claimed invention based on the disclosure in the specification (page 14, top paragraph).

The Office contends that Applicants are not enabled for the multitude of sequences encompassed by Applicants' claims. The Office contends that the individual steps, i.e., generating vectors, transformed plants and screening for plants with increased growth and biomass of the roots, increased floral size and increased seed size is routine, assuming that one skilled in the art is working with one sequence. Given the multitude of sequences that would have to be identified, cloned and subcloned, and tested, undue experimentation would be required to practice the claimed invention given the lack of guidance and/or examples in using non-exemplified nucleic acid sequences. Applicants have not provided guidance for determining which sequence that hybridizes to a second sequence, in which the second sequence encodes a polypeptide exhibiting at least 60% sequence identity to SEQ ID NO:2 would be operable in Applicants' invention. The point is that for one sequence, undue experimentation is not required. But for the thousands of sequences that are encompassed by Applicants' claims, undue experimentation would be required to identify and test the sequences that are operable in Applicants' invention. In addition, Applicants have not specified an assay that can be used to test the putative sequences and Applicants have not included a functional limitation in the claims that reflects the biochemical function of the claimed polypeptide.

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9. Claims 3-6 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated nucleic acid sequence encoding an amino acid sequence comprising SEQ ID NO:2.

10. Claim 6 is allowed.

11. Claims 3-5 are not allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.  
Patent Examiner  
Art Unit 1638  
November 9, 2004

A handwritten signature in cursive script, appearing to read "Amy Nelson", with a long horizontal flourish extending to the right.

AMY J. NELSON, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600